UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

GLENNA C. KISER and WINSTON D. KISER,	)	Case No. 2:21-cv-69
Plaintiffs,	)	Judge Travis R. McDonough
v.	)	Magistrate Judge Cynthia R. Wyrick
TERUMO MEDICAL CORPORATION,	)	
Defendant.	)	

MEMORANDUM OPINION

Before the Court are Defendant Terumo Medical Corporation's ("TMC") motion to exclude the expert opinions of Wenjun Cai, Ph.D. (Doc. 54) and motion for summary judgment (Doc. 55). For the following reasons, the Court will **GRANT** both motions (Docs. 54, 55).

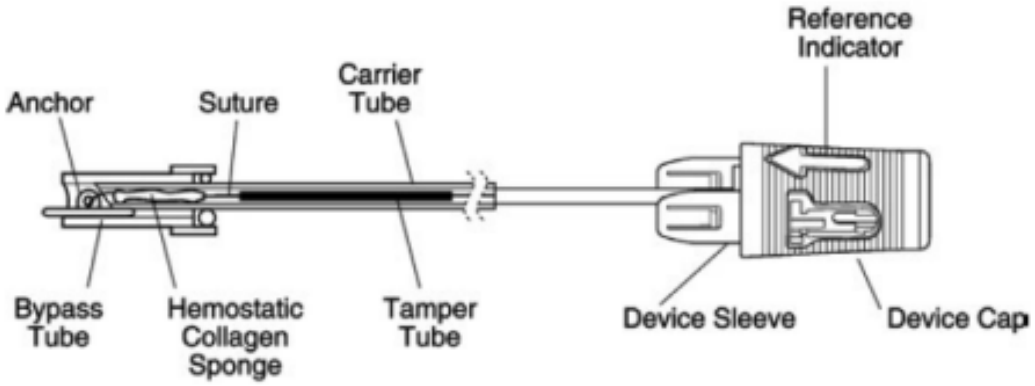
I. BACKGROUND

A. Factual Background

Plaintiff Glenna C. Kiser ("Ms. Kiser") underwent heart-catheterization surgery in 2020. (*See* Doc. 56-3, at 13.) At the end of the procedure, Dr. Mark Borsch—her surgeon—closed the surgical access site in Ms. Kiser's right femoral artery with an Angio-Seal VIP Vascular Closure Device ("Angio-Seal Device"), which TMC designed, manufactured, and sold. (*Id.* at 13, 149; Doc. 56-2, at 8.)

The Angio-Seal Device closes a surgical access site after a heart-catheterization procedure; a surgeon places the device's anchor against the inside blood vessel wall and sets a collagen sponge on top of the surgical cut. (*See* Doc. 56-1, at 3.) A suture connects the anchor and the collagen sponge to seal the incision. (*Id.*) After placing the Angio-Seal Device, the

surgeon tightens the suture by pulling it through the device cap; locks the device cap; and, while maintaining tension by pulling on the suture, cuts the suture twice—once near the top above a marker on the device and once below the patient's skin. (*Id.* at 10–12.) A diagram of the Angio-Seal Device is shown below:



(*Id.* at 6.)

Dr. Borsch, who testified that he has probably used the Angio-Seal Device at least a thousand times, followed these steps. (Doc. 56-3, at 27.) However, after the surgery, the Angio-Seal Device dislodged and became trapped in Ms. Kiser's right femoral artery. (Doc. 56-2, at 18–19.) The trapped device blocked Ms. Kiser's blood flow. (*Id.*) Dr. Borsch's colleague, Dr. Sidney Collins, surgically removed the device. (Doc. 56-3, at 136.) This surgery required a more invasive cut than the heart-catheterization procedure. (*Id.*) According to Ms. Kiser, she continues to suffer from complications of the surgery to remove the device, including leg pain, limited use of her right leg, accumulation of plasma and lymphatic fluid in her right thigh—which required additional surgery—and the placement of a wound vac. (Doc. 1-2, at 10.)

B. Dr. Cai's Expert Report

Plaintiffs retained Wenjun Cai, Ph.D., a materials science and engineering professor at Virginia Tech University, to examine the Angio-Seal Device. (*See* Doc. 57-1.) By the time Dr.

Cai received the Angio-Seal Device, the device had fallen into five pieces: the device's anchor and four separated pieces of the suture. (*See* Doc. 54-9, at 58–59.) The pieces are shown below in an image captured by one of TMC's experts, Dr. Marta Villarraga, who examined the Angio-Seal Device before Dr. Cai:

(Doc. 54-8, at 2.) The roughly spherical object in the upper left portion of the image is the Angio-Seal Device's anchor, and the four broken strands are pieces of the suture. (Doc. 54-9, at 58–59.) Dr. Cai only possessed these five pieces. (*See id.*)

Dr. Cai performed three tests on the Angio-Seal Device, although her report does not specify which component she conducted these tests on, describing the sample only as a

"polymer"[1]: (1) scanning electron microscopy (SEM) imaging; (2) energy dispersive spectroscopy ("EDS"); and (3) image J analysis. (Doc. 57-1, at 1.) In deposition, Dr. Cai testified that she only examined "the larger piece" that "seem[ed] to be surrounded by collagen" and that "[t]he threaded pieces turned out to be very fragile to handle" so she "did not look at them under SEM." (Doc. 54-12, at 141–42, 144.)

SEM imaging uses a highly energetic electron beam to photograph an object. (Doc. 57-1, at 2.) Before conducting SEM imaging, Dr. Cai applied a metal coating to the polymer's surface. (*Id.*) Using SEM imaging, Dr. Cai observed a ductile fracture—where a material deforms and stretches before breaking apart—as opposed to a brittle fracture—where a material breaks apart without deforming or stretching—in the polymer. (*Id.*)

Dr. Cai next performed EDS testing. (*Id.*) EDS testing measures a sample's elemental makeup. Dr. Cai determined that the polymer consisted of 62.7% carbon, 23.7% oxygen, 12.7% nitrogen, 0.6% chloride, and 0.3% sodium. (*Id.*)

Lastly, Dr. Cai measured the polymer's dimensions using image J software—an open-source image-analysis software. (*Id.* at 6.) Analyzing the SEM images using the software, Dr. Cai measured the polymer's diameter at ten different points, garnering measurements from 1.67

[1] A polymer is not a device component; rather, a polymer is a generic term for an arrangement of molecules which create a material, such as a plastic. As discussed below, this is one basis of TMC's motion to exclude Dr. Cai's opinions. *See Infra* Section III.A.i.

millimeters[2] to 2.56 millimeters. (*Id.* at 7.) She concluded that the polymer had an average diameter of 2.11 millimeters with a standard deviation of 0.3 millimeters. (*Id.*)

Dr. Cai did not specify the component on which she performed testing; she merely called it a "polymer" and noted she only used SEM imaging on "the larger" piece. (*Id.* at 1; Doc. 54-12, at 141–42.) She compared the aforementioned data to manufacturing information TMC provided to the Food and Drug Administration ("FDA"). (Doc. 57-1, at 7–11.) Unlike other portions of her report, Dr. Cai's conclusions specifically stated opinions about the suture. (*Id.*) According to these conclusions, "the *suture* examined deviated from the information provided by [TMC] . . . to the FDA." (*Id.* at 9 (emphasis added).) She further opined that "the suture itself was deformed either during the process of loading the suture into the device . . . or due to a malfunction of the tensioner within the device which malformed the suture causing it to develop a ductile fracture." (*Id.*) Dr. Cai identified the malformation as the suture not being of "consistent uniform diameter." (*Id.* at 10.) The standard diameter of the suture in the Angio-Seal Device is 0.3 millimeters. (Doc. 54-21, at 5; Doc. 56-4, at 103.)

According to Dr. Cai, this malformation "caused the stress forces demonstrated in [her] testing that led to the suture developing a ductile fracture" and concluded that "[h]ad the suture been of a uniform diameter and not had this manufacturing defect, it would not have developed the ductile fracture." (Doc. 57-1, at 10.) Finally, Dr. Cai opined that, although TMC tested the suture's tensile strength, "the data provided to the [FDA] was predicated on the suture being loaded in to the device without the underlying defect" and that "failure to appreciate this defect,

[2] Dr. Cai reported these measurements in microns. A micron is one-thousandth of a millimeter, and, for consistency, the Court will convert all measurements to millimeters.

which is a deviation from the information provided to the FDA, [] caused the ductile fracture to occur." (*Id.* at 10–11.)

C. Procedural Background

Ms. Kiser, along with her husband, Plaintiff Winston D. Kiser ("Mr. Kiser"), brought this action in the Circuit Court for Sullivan County, Tennessee, on January 8, 2021, and TMC removed the case to this Court on April 7, 2021. (Doc. 1.) They allege claims under the Tennessee Products Liability Act ("TPLA"), Tenn. Code Ann. § 29-28-101, *et seq.*, for: (1) strict liability; (2) negligence; (3) punitive damages; (4) compensatory damages; and (5) loss of consortium. (*Id.* at 10–13.) TMC now moves for summary judgment (Doc. 55) on all claims against it and also moves to exclude the expert opinions of Dr. Cai. (Doc. 54). These motions are ripe for the Court's review.

II. STANDARDS OF REVIEW

A. Federal Rules of Evidence 702 and 703

Federal Rules of Evidence 702 and 703 govern the admissibility of testimony by expert witnesses. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. According to Rule 703, an expert is permitted to base her opinion on facts or data of which she has been made aware or has personally observed. Fed. R. Evid. 703. The underlying facts or data need not be admissible for the opinion to be admitted, so long as an expert in the field would reasonably rely on them in forming an opinion on the subject. *Id.*

The Sixth Circuit has identified three requirements for an expert's testimony to be admissible under Rule 702: (1) "the witness must be qualified by knowledge, skill, experience, training, or education"; (2) "the testimony must be relevant, meaning that it will assist the trier of fact to understand the evidence or to determine a fact in issue"; and (3) "the testimony must be reliable." *Burgett v. Troy-Bilt, LLC*, 579 F. App'x 372, 376 (6th Cir. 2014) (citing *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008)) (internal quotation marks omitted). With respect to the first requirement, courts consider whether the qualifications "provide a foundation for a witness to answer a specific question," as opposed to considering his or her qualifications in the abstract. *Id.* (citing *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). The party offering the expert testimony must prove the expert's qualifications by a preponderance of the evidence. *Id.* (citing *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008)). Reliability, the third requirement, is assessed by the factors set out in Rule 702 itself—whether the testimony is based on sufficient facts or data, whether the testimony is the product of reliable principles and methods, and whether the principles and methods used were reliably applied. *In re Scrap Metal*, 527 F.3d at 529 (citing Fed. R. Evid. 702). The focus is on reliability rather than "credibility and accuracy." *Superior Prod. P'ship v. Gordon Auto Body Parts Co., Ltd.*, 784 F.3d 311, 323 (6th Cir. 2015) (quoting *In re Scrap Metal*, 527 F.3d at 529). Thus, courts should focus on the methodology employed rather than the conclusions drawn. *Id.*; *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993). In determining whether expert testimony "is the product of reliable principles and methods," Fed. R. Evid. 702(c), courts may consider whether the methods and principles have been and are capable of being tested, whether they have been subjected to peer review and publication, their known or potential rate of error, and whether they are generally accepted within the relevant scientific community. *See*

Daubert, 509 U.S. at 593–94; *see also United States v. Mallory*, 902 F.3d 584, 592–93 (6th Cir. 2018) (noting that all of the factors do not necessarily apply in every case). The inquiry, however, is flexible, and the district court may also consider other factors that bear on the reliability of the expert's testimony. *See Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149–50 (1999) ("[A] trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony."). A rebuttal expert may provide contrasting expert opinions or challenge the methodology utilized by the opposing party's experts in arriving at his conclusions. *E.E.O.C. v. Tepro, Inc.*, 133 F. Supp. 3d 1034, 1048 (E.D. Tenn. 2015).

"[R]ejection of expert testimony is the exception rather than the rule," and "Rule 702 should be broadly interpreted on the basis of whether the use of expert testimony will assist the trier of fact." *Burgett*, 579 F.3d at 376 (citations omitted) ("*Daubert* did not work a seachange over federal evidence law, and the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system.").

A district court may, but need not, hold an evidentiary hearing to aid in the decision of whether to grant a *Daubert* motion. *See Kuhmo*, 526 U.S. at 152 ("The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable." (emphasis in the original)); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 249 (6th Cir. 2001).

B. Summary Judgment

Summary judgment is proper when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a). The Court views the evidence in the light most favorable to the nonmoving party and makes all reasonable inferences in favor of the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp*., 475 U.S. 574, 587 (1986); *Nat'l Satellite Sports, Inc. v. Eliadis Inc*., 253 F.3d 900, 907 (6th Cir. 2001).

The moving party bears the burden of demonstrating that there is no genuine dispute as to any material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Leary v. Daeschner*, 349 F.3d 888, 897 (6th Cir. 2003). The moving party may meet this burden either by affirmatively producing evidence establishing that there is no genuine issue of material fact or by pointing out the absence of support in the record for the nonmoving party's case. *Celotex*, 477 U.S. at 325. Once the movant has discharged this burden, the nonmoving party can no longer rest upon the allegations in the pleadings; rather, it must point to specific facts supported by evidence in the record demonstrating that there is a genuine issue for trial. *Chao v. Hall Holding Co., Inc*., 285 F.3d 415, 424 (6th Cir. 2002).

At summary judgment, the Court may not weigh the evidence; its role is limited to determining whether the record contains sufficient evidence from which a jury could reasonably find for the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248–49 (1986). A mere scintilla of evidence is not enough; the Court must determine whether a fair-minded jury could return a verdict in favor of the non-movant based on the record. *Id.* at 251–52; *Lansing Dairy, Inc. v. Espy*, 39 F.3d 1339, 1347 (6th Cir. 1994). If not, the Court must grant summary judgment. *Celotex*, 477 U.S. at 323.

III. ANALYSIS

TMC moves to exclude the expert opinions of Dr. Cai (Doc. 54) and also moves for summary judgment on all claims against it (Doc. 55).

A. TMC's Motion to Exclude Expert Opinions of Dr. Cai (Doc. 54)

The Court will begin with TMC's motion to exclude the expert testimony of Dr. Cai (Doc. 54) because "under Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects." *Pride v. BIC Corp.*, 218 F.3d 566, 580–81 (6th Cir. 2000) (first citing *Fulton v. Pfizer Hosp. Prods. Grp., Inc.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993); and then citing *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976)). Further, "[i]n all product liability actions, '[a] plaintiff must show that there was something wrong with the product, and trace the plaintiff's injury to the specific defect.'" *Maness v. Boston Sci.*, 751 F. Supp. 2d 962, 968 (E.D. Tenn. 2010) (quoting *King v. Danek Med., Inc.*, 37 S.W.3d 426, 435 (Tenn. Ct. App. 2000)). Dr. Cai is Plaintiffs' only expert providing testimony on the existence of the Angio-Seal Device's specific defect. If her testimony is inadmissible, Plaintiffs cannot meet their burden to prove a specific defect, and the Court must grant summary judgment under Tennessee law.

i. Whether Dr. Cai's Methods are Reliable

TMC first argues that Dr. Cai's methods are unreliable, and therefore inadmissible, because Dr. Cai did not examine the suture. (Doc. 54, at 6.) Plaintiffs argue that Dr. Cai did, in fact, examine the suture, and, in any event, whether she examined the suture goes to the weight of her testimony rather than the reliability of her opinions. (Doc. 58, at 12–15.) According to Plaintiffs, Dr. Cai provided two conclusions: "(1) the suture itself was deformed during the process of loading the suture into the device during manufacturing and (2) the deformity was

overlooked by the party performing the inspection process or due to a malfunction of the tensioner within the device." (*Id.*) Lastly, Plaintiffs argue that "Dr. Cai gives a clear causation opinion when she states that this malfunction caused the deformity and led to the ductile fracture when stress was later placed on the device during its use on Ms. Kiser." (*Id.*)

While a court's role is only to determine whether an expert's testimony is reliable, not whether it is accurate or credible, a court must determine whether an expert's opinion rests on a "reliable foundation" rather than "unsupported speculation." *In re Scrap*, 527 F.3d at 529–30. Even expert testimony based on erroneous facts is generally permitted "when there is some support for those facts in the record." *Id.* at 530. Expert testimony based on "shaky" evidence is admissible, so long as the testimony is not based on "guesses" or "assumptions." *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 393 (6th Cir. 2000). However, a "court is not required to admit expert testimony 'that is connected to existing data only by [an assertion without proof] of the expert'" and "may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Nelson v. Tenn. Gas Pipeline Co.,* 243 F.3d 244, 254 (6th Cir. 2001) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Dr. Cai examined a *polymer* and concluded its diameter ranged from 1.67 millimeters to 2.56 millimeters. (Doc. 57-1, at 6.) She then concluded the *suture's* lack of consistent uniform diameter caused the Angio-Seal Device to fail. (*Id.* at 10.) But Dr. Cai testified that "other than when [she] took [her] cell phone" and "put a ruler next to it," she did not measure the suture, and, when asked to identify the polymer described in her report, Dr. Cai circled the Angio-Seal Device's anchor. (Doc. 54-12, at 25, 161–62; Doc. 54-15, at 2.) The suture's standard diameter is 0.3 millimeters—roughly one-seventh the measured polymer's average diameter. (Doc. 54-21, at 5; Doc. 56-4, at 103.) Only two possibilities explain this discrepancy: either (1) the polymer

Dr. Cai measured in her report was not the suture; or (2) Dr. Cai measured the suture, but photographic evidence forecloses any possibility that her measurements were accurate. Either way, Dr. Cai's methods were unreliable, and her opinion is inadmissible.

a. Whether Dr. Cai Measured the Suture

Plaintiffs claim that Dr. Cai testified that she measured the suture. (Doc. 58, at 13.) She did not. The testimony Plaintiffs cite, coupled with Dr. Cai's additional testimony, show otherwise.

Dr. Cai testified that "other than when [she] took [her] cell phone" and "put a ruler next to it" she did not measure the "threads"—the four fractured pieces of the suture. (Doc. 54-12, at 25.) She did not conduct tensile testing on the suture, did not test the suture's composition, and did not capture SEM images of the suture. (*Id.* at 24–25.) Lastly, when asked "[s]o you never said the suture was 2 millimeters?" Dr. Cai replied "[n]o, I did not say that." (*Id.* at 171.) Rather, it appears that Dr. Cai measured the anchor. (*Id.* at 141–42 (Dr. Cai stating that she only conducted SEM on "the larger piece" that "seem[ed] to be surrounded by collagen"—the anchor).) She identified the polymer described in her report by circling the Angio-Seal Device's anchor. (*See id.* at 161–62; Doc. 54-15, at 2 (Dr. Cai circled the anchor when asked to circle the component her report described as the "polymer").) Plaintiffs even concede that "Dr. Cai only [said] that she did not examine the individual broken pieces of the suture" yet still argue that she measured the suture. (Doc. 58, at 13.) These individual broken pieces of the suture were the only pieces of the suture Dr. Cai possessed; if she did not examine these pieces, she did not examine the suture. (*See* Doc. 54-9, at 58–59.)

If Dr. Cai's testimony allows any doubts to remain that her reference to the "polymer" could actually mean "suture," the images she and Dr. Villarraga captured extinguish them. This

cell-phone image, which Dr. Cai testified is the only measurements she took of the suture, is of the components next to a ruler:

(Doc. 54-7, at 2; Doc. 54-12, at 25.) When Dr. Villarraga examined the suture, she captured images of it next a scale of one millimeter in the corner[3]:

[3] There are several other images of the suture next to this one-millimeter scale, but this image provides the greatest detail.

(Doc. 54-8, at 2.)

It is clear from these images that the polymer Dr. Cai measured is not the suture; she claims to have measured the polymer's diameter at ten points, with measurements ranging between 1.67 millimeters to 2.56 millimeters. (Doc. 57-1, at 7.) Both images show the suture's diameter is far smaller, meaning it could not be the polymer described in her report. The ruler in the cell-phone image is an imperial ruler, meaning there are sixteen equally-spaced marks on the ruler per inch; the space between each mark is equal to one-sixteenth of an inch. One-sixteenth of an inch is equal to 1.5875 millimeters. None of Dr. Cai's ten measurements squares with these images. Even Dr. Cai's smallest measurement of the polymer's diameter—1.67 millimeters—would roughly span the distance between two of the ruler's marks. The suture's

diameter does not even span the thickness of one of the lines, let alone the distance between two lines. This, either alone or together with Dr. Villarraga's image of the suture next to a scale showing that its diameter is less than one millimeter and the above evidence, firmly convinces the Court that whatever Dr. Cai measured was not the suture.

b. Whether Dr. Cai's Methods are Reliable if She Failed to Measure the Suture

Plaintiffs argue that whether Dr. Cai examined the suture is a question of weight for the jury to decide rather than a question of admissibility. (Doc. 58, at 12, 14.) But Dr. Cai's failure to examine the suture renders her methods unreliable and her opinions inadmissible. The "deformity"—in her words, the "malformation"—in Dr. Cai's conclusion is that the suture was not of "consistent uniform diameter." (Doc. 57-1, at 10.) Such a conclusion necessarily rests on an examination of the suture. And, without an examination, Dr. Cai has no basis to conclude there was a deformity, the foundation upon which all her other opinions rest. Dr. Cai clearly states that "had the suture been of uniform diameter . . . it would not have developed the ductile fracture." (*Id.*) But, without examining the suture, she had no basis to draw any conclusions about the suture's diameter and, therefore, the cause of its fracture.

To be sure, Dr. Cai performed tests on *a* polymer—SEM, EDS testing, and image J analysis. (*Id.* at 1.) But the subject polymer cannot have been the suture at issue, and, therefore, her tests cannot support a conclusion regarding the suture's diameter or other characteristics. Even the most scientifically sound tests on a polymer other than the suture at issue bear no relationship to Dr. Cai's conclusions; she may as well have concluded that the device malfunctioned because a pen sitting on her desk measured too wide. In sum, without measuring

the suture, Dr Cai's conclusions are "unsupported speculation," her methods are unreliable, and her opinions are inadmissible.

c. Whether Dr. Cai's Opinions are Reliable, Even if She Measured the Suture

Even if Dr. Cai examined the suture, her methods were unreliable. First, Plaintiffs argue that Dr. Cai "obtain[ed] measurements" of the suture because she took the above cell-phone picture of the suture next to a ruler.[4] (Doc. 57, at 9.) Such a method of examination is unreliable. The ruler in this image contains imperial units, and Dr. Cai's conclusions regarding the polymer's diameter were in *millimeters*. Even so, eyeballing an object smaller than a ladybug by placing that object in a curved container next to a ruler and then concluding that the diameter of that object was not uniform cannot possibly be reliable. Plaintiffs state that, given the suture was brittle, this cell-phone image was the most effective method to "obtain an estimate of the length." (Doc. 57, at 9.) But Dr. Cai's opinion is not based on the suture's length; it is based on its diameter.

If the polymer described in her report was the suture, Dr. Cai's purported measurements cannot be the true diameter of the suture. As discussed above, the undisputed photographic evidence shows that the suture cannot possibly be between 1.67 millimeters to 2.56 millimeters. Given that photographs of the suture foreclose any possibility that Dr. Cai's measurements are the true diameter of the suture, her methods cannot be reliable. *See Greenwell v. Boatwright*, 184 F.3d 492, 497 (6th Cir. 1999) ("Expert testimony, however, is inadmissible when the facts upon which the expert bases his testimony on contradict the evidence.") (citing *United States v.*

[4] Plaintiffs raise this argument in their response to TMC's motion for summary judgment rather than in their response to TMC's motion to exclude. Given whether Dr. Cai measured the suture is necessary for the Court to resolve TMC's motion to exclude, the Court will address this point.

Chaney, 577 F.2d 433, 435 (7th Cir. 1978)); *H.C. Smith Invs. v. Outboard Marine Corp.*, 181 F. Supp. 2d 746, 753 (W.D. Mich. 2002) (excluding expert opinions because the "contradictory record evidence" in the case rendered the expert's conclusions "unreliable and misleading").

Ultimately, Dr. Cai opined that the malformation in the suture was "a clear deviation from the information provided to the FDA that the suture would be of 'consistent uniform diameter.'" (Doc. 57-1, at 10.) Dr. Cai either did not measure the suture or her measurements of the suture are impossible. She offers no other basis to support her assertion that the suture was not consistent in diameter. As a result, Dr. Cai's methods are unreliable, and her opinion is inadmissible. Therefore, the Court will grant TMC's motion to exclude Dr. Cai's testimony (Doc. 54).

B. TMC's Motion for Summary Judgment (Doc. 55)

TMC also moves for summary judgment on all claims against it. (Doc. 55.)

i. Strict Liability and Negligence

Plaintiffs' strict-liability and negligence claims fall under the TPLA.[5] In relevant part, the TPLA provides that a "manufacturer . . . of a product shall not be liable for any injury to a person or property caused by a product unless the product is determined to be in a defective

[5] The TPLA defines "product liability action" as

> [A]ll actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. "Product liability action" includes, but is not limited to, all actions based upon the following theories: **strict liability in tort**; **negligence**; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever.

Tenn. Code Ann. § 29-28-102(6) (emphasis added).

condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). For a plaintiff to succeed in a TPLA claim, she must establish that "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Kines v. Ford Motor Co.*, 558 F. Supp. 3d 614, 627 (W.D. Tenn. 2021) (quoting *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008)).

"As a general rule, an injury of itself is not proof of a defect and thereby raises no presumption of defectiveness." *Fulton*, 872 S.W.2d at 911 (first citing *Gates v. Ford Motor Co.,* 494 F.2d 458, 459 (10th Cir. 1974); and then citing *Mullins v. Seaboard Coastline Ry. Co.,* 517 S.W.2d 198, 201 (Tenn. Ct. App. 1974)). "Likewise, the failure or malfunction of the [product], without more, will not make the defendant liable." *King*, 37 S.W.3d at 435 (citing *Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1298 (M.D. Tenn. 1992)). A plaintiff must show that there was something wrong with the product and must trace the plaintiff's injury to some specific defect in the construction or design of the product. *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL 746823, at *4 (Tenn. Ct. App. Apr. 7, 2004). Lastly, "under Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects." *Pride*, 218 F.3d at 580.

In this case, Plaintiffs cannot establish a specific manufacturing defect. Dr. Cai provided Plaintiffs' only expert testimony and their only evidence of a specific defect. Since the Court has excluded Dr. Cai's testimony, Plaintiffs are left without expert testimony to establish liability. Plaintiffs argue that both Dr. Borsch's and Dr. Collins's testimony support a conclusion that the Angio-Seal Device failed because of a manufacturing defect. (Doc. 57, at 12–13.) But neither Dr. Borsch nor Dr. Collins points to a specific defect, only that Dr. Borsch used the device as

intended. (*See* Doc. 56-3, at 27; Doc. 56-8, at 110.) Accordingly, no reasonable jury could find for Plaintiffs on their TPLA claims.

ii. Compensatory Damages and Punitive Damages

Plaintiffs seek compensatory damages and punitive damages. (Doc. 1-2, at 12–13.) Compensatory damages and punitive damages are not claims; rather, they are remedies for Plaintiffs' TPLA claims. *See Jenkins v. Brown*, No. M2005-02022, 2007 WL 4372166, at *13 (Tenn. Ct. App. Dec. 14, 2007) ("In Tennessee, there can be no claim for punitive damages alone. Thus, without an award of compensatory damages or any other sort of remedial relief, an award of punitive damages cannot stand.") (citations omitted). Because the Court granted summary judgment on Plaintiffs' TPLA claims, the Court will grant summary judgment on these "claims."

iii. Loss of Consortium

Mr. Kiser brings a claim for loss of consortium. (Doc. 1-2, at 13.) "The right to recover for loss of consortium is independent of the spouse's right to recover for the injuries themselves, however, the claim 'will always be "derivative" in the sense that the injuries to his or her spouse are an element are must be proved.'" *Wiley v. Danek Med., Inc.*, No. 95-2542, 1999 WL 33537314, at *9 (W.D. Tenn. May 11, 1999) (quoting *Swafford v. City of Chattanooga,* 743 S.W.2d 174 (Tenn. Ct. App. 1987)). Because the Court granted TMC's motion for summary judgment on all of Ms. Kiser's claims, Mr. Kiser's claim also fails.

IV. CONCLUSION

For the above-stated reasons, TMC's motion to exclude the expert opinions of Dr. Cai (Doc. 54) and motion for summary judgment (Doc. 55) are **GRANTED**. Plaintiffs' claims against TMC will be **DISMISSED WITH PREJUDICE**.

AN APPROPRIATE JUDGMENT WILL ENTER.

/s/ Travis R. McDonough
TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE